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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

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Memorandum

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Subject: No-effects Determination for Thiodicarb for Pacific Anadromous Salmonids

We reviewed the available data and other information for thiodicarb and its potential effects on Pacific anadromous salmonid and their critical habitat. Thiodicarb is a carbamate insecticide/ovicide registered nationally for control of various insect pests on use sites including cotton, soybeans, sweet corn, leafy vegetables, cole crops, ornamentals, tree crops, rights-of-way, grassways, fencerows, and several other sites. Thiodicarb was cited by the Washington Toxics Coalition (WTC) as a pesticide they believe warrants review. The basis of their concern appears to be in the Reregistration Eligibility Decision (RED) of December, 1998, which included an ecological risk assessment for nontarget fish and wildlife. Thiodicarb is moderately toxic to fish (LC50s = 1470 to 4400 ppb) but is very highly toxic to aquatic invertebrates (EC50 = 27 ppb). The primary degradate, methomyl, is moderately to highly toxic to fish (LC50s = 480 to 4400 ppb) and also is very highly toxic to aquatic invertebrates (EC50s = 8 to 88 ppb). The environmental risk assessment concluded that endangered fish might be at direct risk from exposure to the degradate (methomyl) and that most or all crop uses are likely to pose high risks to aquatic invertebrates. Reduction in populations of aquatic invertebrates might adversely affect the food supply of listed Pacific salmon and steelhead.

Based on usage information, however, we conclude that thiodicarb and its degradate will have no effect on any of the 26 listed steelhead and salmon Evolutionarily Significant Units (ESUs) in California and the Pacific Northwest. Thiodicarb is no longer marketed in the Pacific Northwest states. Therefore, the ESUs in Oregon, Washington, and Idaho are not currently at risk. However, should thiodicarb be marketed in any of those states in future years, potential risks will need to be evaluated. The Office of Pesticide Programs will confer with lead agencies in Oregon, Washington, and Idaho annually to monitor any marketing of thiodicarb in the Pacific Northwest. In California, approximately 9360 pounds of active ingredient was used on 13,382 acres in 2001. Major use sites were celery (4825 acres treated), lettuce (3714 acres treated), and cotton (2377 acres treated). However, use has declined from the 156,000 pounds of active ingredient applied in 1997, and there is little use, mostly on leafy vegetables, within any of the 10 listed salmonid ESUs in California. Only one thiodicarb product is used in California, and it can be purchased and used only by Certified Applicators. The product label requires a no-spray buffer and a vegetated filter strip between the application site and any surface waters. Therefore, we believe that endangered salmonids are not at direct risk, because even a minimal reduction of drift and runoff into surface waters will sufficiently reduce the aquatic concentration below the level of concern. Acute risk to aquatic-invertebrate populations does not exceed the level of concern (LOC). The chronic LOC is exceeded for aquatic invertebrates, but chronic risk is not expected because of low thiodicarb usage and because chronic exposure is not expected in flowing waters.

Background

Under section 7 of the Endangered Species Act, the Office of Pesticide Programs (OPP) of the U. S. Environmental Protection Agency (EPA) is required to consult on actions that 'may affect' Federally listed endangered or threatened species or that may adversely modify designated critical habitat. Situations where a pesticide may affect a fish, such as any of the salmonid species listed by the National Marine Fisheries Service (NMFS), include either direct or indirect effects on the fish. Direct effects result from exposure to a pesticide at levels that may cause harm.

Acute Toxicity - Relevant acute data are derived from standardized toxicity tests with lethality as the primary endpoint. These tests are conducted with what is generally accepted as the most sensitive life stage of fish, i.e., very young fish from 0.5-5 grams in weight, and with species that are usually among the most sensitive. These tests for pesticide registration include analysis of observable sublethal effects as well. The intent of acute tests is to statistically derive a median effect level; typically the effect is lethality in fish (LC50) or immobility in aquatic invertebrates (EC50). Typically, a standard fish acute test will include concentrations that cause

no mortality, and often no observable sublethal effects, as well as concentrations that would cause 100% mortality. By looking at the effects at various test concentrations, a dose-response curve can be derived, and one can statistically predict the effects likely to occur at various pesticide concentrations; a well done test can even be extrapolated, with caution, to concentrations below those tested (or above the test concentrations if the highest concentration did not produce 100% mortality).

OPP typically uses qualitative descriptors to describe different levels of acute toxicity, the most likely kind of effect of modern pesticides (Table 1). These are widely used for comparative purposes, but must be associated with exposure before any conclusions can be drawn with respect to risk. Pesticides that are considered highly toxic or very highly toxic are required to have a label statement indicating that level of toxicity. The FIFRA regulations [40CFR158.490(a)] do not require calculating a specific LC50 or EC50 for pesticides that are practically non-toxic; the LC50 or EC50 would simply be expressed as >100 ppm. When no lethal or sublethal effects are observed at 100 ppm, OPP considers the pesticide will have "no effect" on the species.

Table 1. Qualitative descriptors for categories of fish and aquatic invertebrate toxicity (from Zucker, 1985)

LC50 or EC50	Category description
< 0.1 ppm	Very highly toxic
0.1- 1 ppm	Highly toxic
>1 < 10 ppm	Moderately toxic
> 10 < 100 ppm	Slightly toxic
> 100 ppm	Practically non-toxic

Comparative toxicology has demonstrated that various species of scaled fish generally have equivalent sensitivity, within an order of magnitude, to other species of scaled fish tested under the same conditions. Sappington et al. (2001), Beyers et al. (1994) and Dwyer et al. (1999), among others, have shown that endangered and threatened fish tested to date are similarly sensitive, on an acute basis, to a variety of pesticides and other chemicals as their non-endangered counterparts.

Chronic Toxicity - OPP evaluates the potential chronic effects of a pesticide on the basis of several types of tests. These tests are often required for registration, but not always. If a pesticide has essentially no acute toxicity at relevant concentrations, or if it degrades very rapidly in water, or if the nature of the use is such that the pesticide will not reach

water, then chronic fish tests may not be required [40CFR158.490]. Chronic fish tests primarily evaluate the potential for reproductive effects and effects on the offspring. Other observed sublethal effects are also required to be reported. An abbreviated chronic test, the fish early-life stage test, is usually the first chronic test conducted and will indicate the likelihood of reproductive or chronic effects at relevant concentrations. If such effects are found, then a full fish life-cycle test will be conducted. If the nature of the chemical is such that reproductive effects are expected, the abbreviated test may be skipped in favor of the full life-cycle test. These chronic tests are designed to determine a "no observable effect level" (NOEL) and a "lowest observable effect level" (LOEL). A chronic risk requires not only chronic toxicity, but also chronic exposure, which can result from a chemical being persistent and resident in an environment (e.g., a pond) for a chronic period of time or from repeated applications that transport into any environment such that exposure would be considered "chronic".

As with comparative toxicology efforts relative to sensitivity for acute effects, EPA, in conjunction with the U. S. Geological Survey, has a current effort to assess the comparative toxicology for chronic effects also. Preliminary information indicates, as with the acute data, that endangered and threatened fish are again of similar sensitivity to similar non-endangered species.

Metabolites and Degradates - Information must be reported to OPP regarding any pesticide metabolites or degradates that may pose a toxicological risk or that may persist in the environment [40CFR159.179]. Toxicity and/or persistence test data on such compounds may be required if, during the risk assessment, the nature of the metabolite or degradate and the amount that may occur in the environment raises a concern. If actual data or structure-activity analyses are not available, the requirement for testing is based upon best professional judgement.

Inert Ingredients - OPP does take into account the potential effects of what used to be termed "inert" ingredients, but which are beginning to be referred to as "other ingredients". OPP has classified these ingredients into several categories. A few of these, such as nonylphenol, can no longer be used without including them on the label with a specific statement indicating the potential toxicity. Based upon our internal databases, we can find no product in which nonylphenol is now an ingredient. Many others, including such ingredients as clay, soybean oil, many polymers, and chlorophyll, have been evaluated through structure-activity analysis or data and determined to be of minimal or no toxicity. There exist also two additional lists, one for inerts with potential toxicity which are considered a testing priority, and one for inerts unlikely to be toxic, but which cannot yet be said to have negligible toxicity. Any new inert ingredients are required to undergo testing unless it can

be demonstrated that testing is unnecessary.

The inert efforts in OPP are oriented only towards toxicity at the present time, rather than risk. It should be noted, however, that very many of the inerts are in exceedingly small amounts in pesticide products. While some surfactants, solvents, and other ingredients may be present in fairly large amounts in various products, many are present only to a minor extent. These include such things as coloring agents, fragrances, and even the printers ink on water soluble bags of pesticides. Some of these could have moderate toxicity, yet still be of no consequence because of the negligible amounts present in a product. If a product contains inert ingredients in sufficient quantity to be of concern, relative to the toxicity of the active ingredient, OPP attempts to evaluate the potential effects of these inerts through data or structure-activity analysis, where necessary.

For a number of major pesticide products, testing has been conducted on the formulated end-use products that are used by the applicator. The results of fish toxicity tests with formulated products can be compared with the results of tests on the same species with the active ingredient only. A comparison of the results should indicate comparable sensitivity, relative to the percentage of active ingredient in the technical versus formulated product, if there is no extra activity due to the combination of inert ingredients. We note that the "comparable" sensitivity must take into account the natural variation in toxicity tests, which is up to 2-fold for the same species in the same laboratory under the same conditions, and which can be somewhat higher between different laboratories, especially when different stocks of test fish are used.

The comparison of formulated product and technical ingredient test results may not provide specific information on the individual inert ingredients, but rather is like a "black box" which sums up the effects of all ingredients. We consider this approach to be more appropriate than testing each individual inert and active ingredient because it incorporates any additivity, antagonism, and synergism effects that may occur and which might not be correctly evaluated from tests on the individual ingredients. We do note, however, that we do not have aquatic data on most formulated products, although we often have testing on one or perhaps two formulations of an active ingredient.

Risk - An analysis of toxicity, whether acute or chronic, lethal or sublethal, must be combined with an analysis of how much will be in the water, to determine risks to fish. Risk is a combination of exposure and toxicity. Even a very highly toxic chemical will not pose a risk if there is no exposure, or very minimal exposure relative to the toxicity. OPP uses a variety of chemical fate and transport data to develop "estimated environmental concentrations" (EECs) from a suite of established models. The development of aquatic EECs is a tiered process.

The first tier screening model for EECs is with the GENEEC program, developed within OPP, which uses a generic site (in Yazoo, MS) to stand for any site in the U. S. The site choice was intended to yield a maximum exposure, or "worst-case," scenario applicable nationwide, particularly with respect to runoff. The model is based on a 10 hectare watershed that surrounds a one hectare pond, two meters deep. It is assumed that all of the 10 hectare area is treated with the pesticide and that any runoff would drain into the pond. The model also incorporates spray drift, the amount of which is dependent primarily upon the droplet size of the spray. OPP assumes that if this model indicates no concerns when compared with the appropriate toxicity data, then further analysis is not necessary as there would be no effect on the species.

It should be noted that prior to the development of the GENEEC model in 1995, a much more crude approach was used to determining EECs. Older reviews and Reregistration Eligibility Decisions (REDs) may use this approach, but it was excessively conservative and does not provide a sound basis for modern risk assessments. For the purposes of endangered species consultations, we will attempt to revise this old approach with the GENEEC model, where the old screening level raised risk concerns.

When there is a concern with the comparison of toxicity with the EECs identified in GENEEC model, a more sophisticated PRZM-EXAMS model is run to refine the EECs if a suitable scenario has been developed and validated. The PRZM-EXAMS model was developed with widespread collaboration and review by chemical fate and transport experts, soil scientists, and agronomists throughout academia, government, and industry, where it is in common use. As with the GENEEC model, the basic model remains as a 10 hectare field surrounding and draining into a 1 hectare pond. Crop scenarios have been developed by OPP for specific sites, and the model uses site-specific data on soils, climate (especially precipitation), and the crop or site. Typically, site-scenarios are developed to provide for a worst-case analysis for a particular crop in a particular geographic region. The development of site scenarios is very time consuming; scenarios have not yet been developed for a number of crops and locations. OPP attempts to match the crop(s) under consideration with the most appropriate scenario. For some of the older OPP analyses, a very limited number of scenarios were available.

One area of significant weakness in modeling EECs relates to residential uses, especially by homeowners, but also to an extent by commercial applicators. There are no usage data in OPP that relate to pesticide use by homeowners on a geographic scale that would be appropriate for an assessment of risks to listed species. For example, we may know the maximum application rate for a lawn pesticide, but we do not know the size of the lawns, the proportion of the area in lawns, or the percentage of lawns that may be treated in a given geographic area. There is limited

information on soil types, slopes, watering practices, and other aspects that relate to transport and fate of pesticides. We do know that some homeowners will attempt to control pests with chemicals and that others will not control pests at all or will use non-chemical methods. We would expect that in some areas, few homeowners will use pesticides, but in other areas, a high percentage could. As a result, OPP has insufficient information to develop a scenario or address the extent of pesticide use in a residential area. It is also important to note that pesticides used in urban areas can be expected to transport considerable distances if they should run off on to concrete or asphalt, such as with streets (e.g., TDK Environmental, 1991). This makes any quantitative analysis very difficult to address aquatic exposure from home use. It also indicates that a no-use or no-spray buffer approach for protection, which we consider quite viable for agricultural areas, may not be particularly useful for urban areas.

Finally, the applicability of the overall EEC scenario, i.e., the 10 hectare watershed draining into a one hectare farm pond, may not be appropriate for a number of T&E species living in rivers or lakes. This scenario is intended to provide a "worst-case" assessment of EECs, but very many T&E fish do not live in ponds, and very many T&E fish do not have all of the habitat surrounding their environment treated with a pesticide. OPP does believe that the EECs from the farm pond model do represent first order streams, such as those in headwaters areas (Effland, et al. 1999). In many agricultural areas, those first order streams may be upstream from pesticide use, but in other areas, or for some non-agricultural uses such as forestry, the first order streams may receive pesticide runoff and drift. However, larger streams and lakes will very likely have lower, often considerably lower, concentrations of pesticides due to more dilution by the receiving waters. In addition, where persistence is a factor, streams will tend to carry pesticides away from where they enter into the streams, and the models do not allow for this. The variables in size of streams, rivers, and lakes, along with flow rates in the lotic waters and seasonal variation, are large enough to preclude the development of applicable models to represent the diversity of T&E species' habitats. We can simply qualitatively note that the farm pond model is expected to overestimate EECs in larger bodies of water.

Indirect Effects - We also attempt to protect listed species from indirect effects of pesticides. We note that there is often not a clear distinction between indirect effects on a listed species and adverse modification of critical habitat (discussed below). By considering indirect effects first, we can provide appropriate protection to listed species even where critical habitat has not been designated. In the case of fish, the indirect concerns are routinely assessed for food and cover.

The primary indirect effect of concern would be for the food source for listed fish. These are best represented by potential

effects on aquatic invertebrates, although aquatic plants or plankton may be relevant food sources for some fish species. However, it is not necessary to protect individual organisms that serve as food for listed fish. Thus, our goal is to ensure that pesticides will not impair populations of these aquatic arthropods. In some cases, listed fish may feed on other fish. Because our criteria for protecting the listed fish species is based upon the most sensitive species of fish tested, then by protecting the listed fish species, we are also protecting the species used as prey.

In general, but with some exceptions, pesticides applied in terrestrial environments will not affect the plant material in the water that provides aquatic cover for listed fish. Application rates for herbicides are intended to be efficacious, but are not intended to be excessive. Because only a portion of the effective application rate of an herbicide applied to land will reach water through runoff or drift, the amount is very likely to be below effect levels for aquatic plants. Some of the applied herbicides will degrade through photolysis, hydrolysis, or other processes. In addition, terrestrial herbicide applications are efficacious in part, due to the fact that the product will tend to stay in contact with the foliage or the roots and/or germinating plant parts, when soil applied. With aquatic exposures resulting from terrestrial applications, the pesticide is not placed in immediate contact with the aquatic plant, but rather reaches the plant indirectly after entering the water and being diluted. Aquatic exposure is likely to be transient in flowing waters. However, because of the exceptions where terrestrially applied herbicides could have effects on aquatic plants, OPP does evaluate the sensitivity of aquatic macrophytes to these herbicides to determine if populations of aquatic macrophytes that would serve as cover for T&E fish would be affected.

For most pesticides applied to terrestrial environment, the effects in water, even lentic water, will be relatively transient. Therefore, it is only with very persistent pesticides that any effects would be expected to last into the year following their application. As a result, and excepting those very persistent pesticides, we would not expect that pesticidal modification of the food and cover aspects of critical habitat would be adverse beyond the year of application. Therefore, if a listed salmon or steelhead is not present during the year of application, there would be no concern. If the listed fish is present during the year of application, the effects on food and cover are considered as indirect effects on the fish, rather than as adverse modification of critical habitat.

Designated Critical Habitat - OPP is also required to consult if a pesticide may adversely modify designated critical habitat. In addition to the indirect effects on the fish, we consider that the use of pesticides on land could have such an effect on the critical habitat of aquatic species in a few

circumstances. For example, use of herbicides in riparian areas could affect riparian vegetation, especially woody riparian vegetation, which possibly could be an indirect effect on a listed fish. However, there are very few pesticides that are registered for use on riparian vegetation, and the specific uses that may be of concern have to be analyzed on a pesticide by pesticide basis. In considering the general effects that could occur and that could be a problem for listed salmonids, the primary concern would be for the destruction of vegetation near the stream, particularly vegetation that provides cover or temperature control, or that contributes woody debris to the aquatic environment. Destruction of low growing herbaceous material would be a concern if that destruction resulted in excessive sediment loads getting into the stream, but such increased sediment loads are insignificant from cultivated fields relative to those resulting from the initial cultivation itself. Increased sediment loads from destruction of vegetation could be a concern in uncultivated areas. Any increased pesticide load as a result of destruction of terrestrial herbaceous vegetation would be considered a direct effect and would be addressed through the modeling of estimated environmental concentrations. Such modeling can and does take into account the presence and nature of riparian vegetation on pesticide transport to a body of water.

Risk Assessment Processes - All of our risk assessment procedures, toxicity test methods, and EEC models have been peer-reviewed by OPP's Science Advisory Panel. The data from toxicity tests and environmental fate and transport studies undergo a stringent review and validation process in accordance with "Standard Evaluation Procedures" published for each type of test. In addition, all test data on toxicity or environmental fate and transport are conducted in accordance with Good Laboratory Practice (GLP) regulations (40 CFR Part 160) at least since the GLPs were promulgated in 1989.

The risk assessment process is described in "Hazard Evaluation Division - Standard Evaluation Procedure - Ecological Risk Assessment" by Urban and Cook (1986) (termed Ecological Risk Assessment SEP below), which has been separately provided to National Marine Fisheries Service staff. Although certain aspects and procedures have been updated throughout the years, the basic process and criteria still apply. In a very brief summary: the toxicity information for various taxonomic groups of species is quantitatively compared with the potential exposure information from the different uses and application rates and methods. A risk quotient of toxicity divided by exposure is developed and compared with criteria of concern. The criteria of concern presented by Urban and Cook (1986) are presented in Table 2.

Table 2. Risk-quotient criteria for fish and aquatic invertebrates

Test data	Risk quotient	Presumption
Acute LC50	>0.5	Potentially high acute risk
Acute LC50	>0.1	Risk that may be mitigated through restricted use classification
Acute LC50	>0.05	Endangered species may be affected acutely, including sublethal effects
Chronic NOEC	>1	Chronic risk; endangered species may be affected chronically, including reproduction and effects on progeny
Acute invertebrate LC50	>0.5	May be indirect effects on T&E fish through food supply reduction
Aquatic plant acute EC50	>0.5	May be indirect effects on aquatic vegetative cover for T&E fish

The Ecological Risk Assessment SEP (pages 2-6) discusses the quantitative estimates of how the acute toxicity data, in combination with the slope of the dose-response curve, can be used to predict the percentage mortality that would occur at the various risk quotients. The discussion indicates that using a "safety factor" of 10, as applies for restricted use classification, one individual in 30,000,000 exposed to the concentration would be likely to die. Using a "safety factor" of 20, as applies to aquatic T&E species, would exponentially increase the margin of safety. It has been calculated by one pesticide registrant (without sufficient information for OPP to validate that number), that the probability of mortality occurring when the LC50 is 1/20th of the EEC is 2.39×10^{-9} , or less than one individual in ten billion. It should be noted that the discussion (originally part of the 1975 regulations for FIFRA) is based upon slopes of primarily organochlorine pesticides, stated to be 4.5 probits per log cycle at that time. As organochlorine pesticides were phased out, OPP undertook an analysis of more current pesticides based on data reported by Johnson and Finley (1980), and determined that the "typical" slope for aquatic toxicity tests for the "more current" pesticides was 9.95. Because the slopes are based upon logarithmically transformed data, the probability of mortality for a pesticide with a 9.95 slope is again exponentially less than for the originally analyzed slope of 4.5.

The above discussion focuses on mortality from acute

toxicity. OPP is concerned about other direct effects as well. For chronic and reproductive effects, our criteria ensures that the EEC is below the no-observed-effect-level, where the "effects" include any observable sublethal effects. Because our EEC values are based upon "worst-case" chemical fate and transport data and a small farm pond scenario, it is rare that a non-target organism would be exposed to such concentrations over a period of time, especially for fish that live in lakes or in streams (best professional judgement). Thus, there is no additional safety factor used for the no-observed-effect-concentration, in contrast to the acute data where a safety factor is warranted because the endpoints are a median probability rather than no effect.

Sublethal Effects - With respect to sublethal effects, Tucker and Leitzke (1979) did an extensive review of existing ecotoxicological data on pesticides. Among their findings was that sublethal effects as reported in the literature did not occur at concentrations below one-fourth to one-sixth of the lethal concentrations, when taking into account the same percentages or numbers affected, test system, duration, species, and other factors. This was termed the "6x hypothesis". Their review included cholinesterase inhibition, but was largely oriented towards externally observable parameters such as growth, food consumption, behavioral signs of intoxication, avoidance and repellency, and similar parameters. Even reproductive parameters fit into the hypothesis when the duration of the test was considered. This hypothesis supported the use of lethality tests for use in assessing ecotoxicological risk, and the lethality tests are well enough established and understood to provide strong statistical confidence, which can not always be achieved with sublethal effects. By providing an appropriate safety factor, the concentrations found in lethality tests can therefore generally be used to protect from sublethal effects.

In recent years, Moore and Waring (1996) challenged Atlantic salmon with diazinon and observed effects on olfaction as relates to reproductive physiology and behavior. Their work indicated that diazinon could have sublethal effects of concern for salmon reproduction. However, the nature of their test system, direct exposure of olfactory rosettes, could not be quantitatively related to exposures in the natural environment. Subsequently, Scholz et al. (2000) conducted a non-reproductive behavioral study using whole Chinook salmon in a model stream system that mimicked a natural exposure that is far more relevant to ecological risk assessment than the system used by Moore and Waring (1996). The Scholz et al. (2000) data indicate potential effects of diazinon on Chinook salmon behavior at very low levels, with statistically significant effects at nominal diazinon exposures of 1 ppb, with apparent, but non-significant effects at 0.1 ppb.

It would appear that the Scholz et al (2000) work contradicts the 6x hypothesis. The research design, especially

the nature and duration of exposure, of the test system used by Scholz et al (2000), along with a lack of dose-response, precludes comparisons with lethal levels in accordance with 6x hypothesis as used by Tucker and Leitzke (1979). Nevertheless, it is known that olfaction is an exquisitely sensitive sense. And this sense may be particularly well developed in salmon, as would be consistent with its use by salmon in homing (Hasler and Scholz, 1983). So the contradiction of the 6x hypothesis is not surprising. As a result of these findings, the 6x hypothesis needs to be re-evaluated with respect to olfaction. At the same time, because of the sensitivity of olfaction and because the 6x hypothesis has generally stood the test of time otherwise, it would be premature to abandon the hypothesis for other sublethal effects until there are additional data.

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